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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,123	10/20/2000	Paul R. Lesch JR.	8066-057	6851
28765	7590	06/27/2006		
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006				
			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/692,123

Applicant(s)

LESCH, PAUL R.

Examiner

Christopher D. Koharski

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-13 and 15-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13 and 15-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges amendments to the specification, drawings, and amended claim 5. Currently claims 1-7, 9-13 and 15-30 are pending for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-10, 12-13, 16-20, 22-28, and 30 are rejected under 35 U.S.C 102(b) as being anticipated by Wardlaw (4,258,713). Wardlaw discloses an automatic hypodermic syringe.

Regarding claim 1, 17, 18 and 30, Schluter et al. discloses a *jet injector* for *highspeed* injection (see abstract) of a medicament with a cylindrical tube, a first and second stopper, wherein the medicament is between the stoppers, and once triggered the first stopper pushes the second stopper through a needle creating a fluid path for insertion into the body (Figures 1, 5A).

Regarding claims 2-6, 9-10, 12-13, and 16, Schluter et al. discloses that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figures 5A-5B). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 5A).

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The lumen of the tube is cylindrical and configured to fire via an injector system to expel the medicament (Figure 1).

Regarding claims 19-20, 22-28, Schluter et al. discloses an injection system in that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figures 5A-5B). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 5A).

Claim Rejections - 35 USC § 102

Regarding claim 1, 17, 18, and 30, Wardlaw et al. discloses an injector (see abstract) of a medicament with a cylindrical tube, a first and second stopper, wherein the medicament is between the stoppers, and once triggered the first stopper pushes the second stopper through a needle creating a fluid path for insertion into the body (Figure 1).

Regarding claims 2-6, 9-10, 12-13, and 16, Wardlaw et al. discloses that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figure 1). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 1). The lumen of the tube is cylindrical and configured to fire via an injector system to expel the medicament (Figure 1).

Regarding claims 19-20, 22-28, Wardlaw et al. discloses an injection system in that the movement of the stoppers (second stopper with an are that is designed for needle piercing) compresses the medicament through the needle and second piercable

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stopper (Figure 1). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 11, 15, 21, and 29 are rejected under 35 U.S.C 103(a) as being unpatentable over Schluter et al. in view of Tanaka et al. (5,865,799). Schluter et al. meets the claim limitations as described above but does not include a third stopper, with a recess, and mixing of insoluble particles.

However, Tanaka et al. teaches a pre-filled syringe. Regarding claim 7, 11, 15 21 and 29, Tanaka et al. discloses a third stopper, and an enlarged portion, that is used to mix particles prior to injection (Figures 1 and 5).

At the time of the invention, it would have been obvious to use the stopper system of Tanaka et al. with the system of Schluter et al. because the addition of a third

stopper and enlarged portion allows for different drug combination doses to be injected. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Tanaka et al.

Response to Arguments

Applicant's arguments, see Remarks, filed 5/30/2006, with respect to the rejection(s) of claim(s) 1-7, 9-13 and 15-30 under Malay et al. (5,415,648) have been fully considered and are persuasive. However Applicant is reminded of the Webster's definition of **jet** "...A: high-velocity fluid stream forced under pressure out of a small-diameter opening or nozzle; B: An outlet, such as a nozzle, used for emitting such a stream, C: To propel outward or squirt, as under pressure..." and **injector** "...to introduce (a drug or vaccine, for example) into a body part, especially by means of a syringe..." As currently claimed Applicant's "jet injector" is capable of being met by any standard hypodermic syringe, which is capable of meeting the definition above and will be interpreted as such (see above rejection). The current rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of Schluter et al., Tanaka et al., Wardlaw.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on Monday through Friday 7:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/18/2006

[Date]

ckp

Christopher Koharski
Examiner
Art Unit 3763



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
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